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K096612

510(K) SUMMARY

JUL 2 4 2009

(As Required by Section 807.92 (c))

1. **Submitter**

Name:	Unicare Biomedical, Inc.
Address:	22971-B Triton Way, Laguna Hills, CA 92653
Contact:	Stan Yang, 949-643-6707
Date:	March 3, 2009

2. **Device Name**

Trade Name:	Benacel® Dental Dressing
Common Name:	Wound Dressing
Classification Name:	Dressing
Device Classification:	Unclassified

3. **Predicate Devices**

SaliCept®, "Sock It" oral pain gel, Hemcon®

4. **Device Description**

Benacel® Dental Dressing is an absorbable wound dressing made of oxidized regenerated cellulose material. Upon contact with moist oral mucosa, the material dissolves and transforms into a gelatinous material. By applying gentle pressure at this time, the material will adhere to the wound and form a barrier, protecting the wound from further irritation and pain. Benacel® Dental Dressing is sterile packaged and supplied in a variety of configurations and sizes.

5. **Intended Use**

Benacel® Dental Dressing is intended for use as a wound dressing in extraction sites and the management of alveolar osteitis (dry socket) and may be used as a wound dressing for the temporary management of oral surgical wounds, such as operative, postoperative, donor sites, and traumatic injuries. Benacel® Dental Dressing may also be used as a wound dressing for the management and protection of oral lesions,

K090612

including sores, ulcers, and injuries, such as cuts, lacerations and abrasions of the oral mucosa.

6. **Comparison with Predicate Devices**

Benacel® Dental Dressing is substantially equivalent to devices currently in US commercial distribution, including SaliCept®, "Sock It" oral pain gel and Hemcon®, These products are made of biocompatible wound dressing material with similar performance.

7. **Device Testing**

In vitro and in vivo tests demonstrate that Benacel® Dental Dressing performs substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Stan Yang
Vice President
Unicare Biomedical, Incorporated
22971 Triton Way, Unit B
Laguna Hills, California 92653

JUL 24 2009

Re: K090612
Trade/Device Name: Benacel® Dental Dressing
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MGQ
Dated: July 15, 2009
Received: July 21, 2009

Dear Mr. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

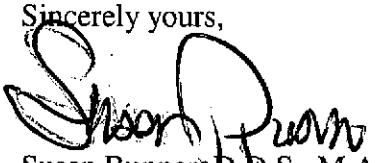
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090612

1 of 1

Indications for Use

510(k) Number (if known): K090612

Device Name: Benacel® Dental Dressing

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090612